Summary of Public Comments

Consultation on fee provisions of the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act
August 11, 2016

Speaker 1: Mike Walls, American Chemistry Council

I'm Mike Walls with the American Chemistry Council. Thank you very much for the opportunity to participate in this discussion today. The American Chemistry Council certainly appreciates this opportunity to have a discussion with the agency and a dialogue with our industry colleagues about some of the options to set fees. ACC and its members supported the fee provisions of the Lautenberg Act. We did so because we recognize that the agency needs additional resources to meet the requirements of the act and ensure a steady stream of risk-based decisions under the act. This is a key goal of the act, and we are committed to working with the agency to achieve a workable fee program.

The fee provisions contemplate some significant additional resources, and the burden imposed on the regulatory community in fees is offset by the expectation that the agency is going to meet its deadlines under the act and be able to efficiently and effectively prioritize and evaluate the risks and regulate as necessary. At the same time, we also recognize that the act itself imposes some very real limitations on the agency. We know that the fees attach only to specific activities and can only be used to defray the costs of specific activities. There are also some practical constraints on the agency here. The Lautenberg Act represents clear direction from Congress that EPA should continue to foster innovation. It is possible to imagine a scenario where fees could be set so high that they would actually discourage innovation. Reconciling some of that policy direction provided by Congress raises some challenges that need to be addressed.

I would like to focus my comments in three areas, the first being the fundamental need for information on EPA's current and anticipated costs in administering the act. Second, I would like to address the need to achieve the objective of a fair, equitable, simple and efficient system. Finally, I will make some specific comments on fees to defray the costs associated with administering Sections 4, 5, and 6.

With respect to the current and anticipated costs, the only benchmark we really have right now is the PMN fee program. I had understood the PMN fees, which are at $2,500 a pop, were generating about a million dollars a year. The Lautenberg Act requires the agency to assess fees that are sufficient and not more than are reasonably necessary. Additional information is needed to understand what is sufficient and not more than reasonably necessary. There is a

significant level of detail just to get to the calculation of what value represents 25 percent of the agency's costs. At the present time, based on the President's budget and EPA's budget submission, it is not possible for the public to pull out the costs of administering TSCA, much less the costs of administering these specific sections. It appears, based on the FY '16 budget, that TSCA appropriations total some $56 million. It's not clear if that amount is used exclusively for these sections, exclusively for TSCA implementation itself, or also applied to funding or the support of other non-TSCA programs that are within the agency's discretionary authority.

In addition, the audit requirements of section 26 contemplate the need for a higher level of transparency about not only the appropriations, but also fees revenue and the expenses associated with that. Understanding the benchmark number we're trying to get to poses a fundamental challenge. On the basis of the appropriation figure of $56 million, roughly 25 percent would be $14 million. We will need direction from the agency on whether that is the initial target or whether the costs associated with administering those provisions will be higher.

With respect to achieving a fair, equitable, simple and efficient fee program, we, like EPA, believe the fees program must have these characteristics. We think that fees ought to be assessed for specific services and should reflect the level of effort that EPA expends in taking action with respect to a submission or a substance. We think the fees ought to attach at specific points, such as they do now in submission of a PMN or a manufacturer request for risk evaluation. Some fees, like those for Section 6 risk evaluations, should not be fully paid until EPA completes the activity. It is important to provide an incentive to the agency to meet the deadlines established in the law for risk evaluations.

We also believe the agency should consider the potential impact on innovation and competitive standing in determining fees. As I mentioned earlier, the fees should not be set at a level that establishes a disincentive to bringing new chemicals forward. In part, old TSCA established the United States as a preferred geography for bringing new chemicals to market. It arguably conferred a significant competitive advantage on the United States and the U.S. chemical industry. We believe we must not lose that advantage. Implementation of the Lautenberg Act provides an important opportunity to think about the impact of fees on that process.

We believe EPA's current approach to fees for small businesses seems workable. The additional requirement in the Lautenberg Act to consult the Small Business Administration may suggest that something like an SBREFA panel might be recommended in order to address the needs of the small business community. We believe there will be a need to develop some clear, readily available guidance on the fee program overall to enable the regulated community to

understand what is the basis for fees, their due dates, fee reduction opportunities, refunds, etc.

I'd like to close with some specific comments on fees related to Sections 4, 5, and 6. Despite having the authorities to do so under old TSCA, EPA's policy is not to assess those associated with the submission of Section 4 data. We think there are valid reasons to continue that policy under the Lautenberg Act. The data generated under Section 4 is developed at the expense of manufacturers and now potentially processors. Charging fees for the submission of Section 4 information effectively charges that manufacturer or processor a second time.

With respect to Section 5 fees, we believe the agency should establish lower fees or none for significant new use notices. Hazard in those cases has been assessed in the context of a PMN, and those submissions should require a lower level of effort than a PMN review. We believe the agency has to work to avoid creating a disincentive through the fee system to claim the benefits of the PMN exemptions. Specifically, the agency may wish to consider charging no fees for exemption notices. We also think that there may be an opportunity for the agency to provide credit for specific reviews conducted prior to PMN assessments, specifically about sustainable futures reviews and what are the links there.

And under Section 6, we believe fees have to be uniform. The law allows for consortia to pay fees associated with Section 6b activities. The fee systems ought to allow the freedom and flexibility to allocate those as they determine fit. In other words, there may be a role for the agency in helping assess disputes in terms of nonpayment of a fee. That requires us to think about how to treat late entrance in the case of the risk evaluation, but in general, we believe that there are opportunities for consortia to work out the fee payment issue on their own.

Fees should be assessed at specific stages in the process to create an incentive to complete work by the statutory deadline. There also needs to be a transparent basis for the assessment of fees for manufacturer requested evaluations that is 50 percent for work plan chemicals and 100 percent for other requests. Again, that goes back to my first point about having the information necessary to understand the cost this poses to the manufacturer.

I'd just make one final comment with respect to manufacturer request. This gets to an issue that I understand was raised several times over the last two days of comments with respect to the conditions of use and the scope of EPA's evaluation. At some point, we are going to have to have some clarity about whether a manufacturer risk evaluation is limited to the conditions of use raised by that manufacturer in the request or whether or not the agency has the authority to expand the scope of that evaluation. That may have consequences for the fee system. Thank you very much for the opportunity.

Speaker 2: Derek Swick, American Petroleum Institute

I'm Derek Swick with the American Petroleum Institute. I would like to first thank EPA for facilitating these stakeholder dialogues. API hopes that EPA will continue this type of stakeholder engagement as it implements the Lautenberg Act. Similar to the comments made by the American Chemistry Council, API supports a reasonable and equitable fee system. We would like to offer a few general comments, and then I'll address the charge questions.

As a general principle, we encourage EPA to be very transparent with the fees that are developed in terms of the structure and how those fees map to various elements of the implementation plan by the different sections of the statute. We hope that the agency will very clearly explain how any fees are derived. And in terms of how the fees should be applied to the various parts of the statute, we think that as a principle, the fee should be proportional to the amount of work that EPA is going to need to do for the review or the evaluation or generally the agency activity and certainly, we would not support a fee structure that would be based on volume.

Along those lines, we think that it's practical for EPA to focus its system on payments that are associated with specific TSCA submissions or requests. I think you do this now for the PMN process. A fee that would apply to multiple manufacturers or manufactures and processors and is not linked to a specific submission or other obligations would be very difficult for EPA to administer, and we recognize that it will be hard up front to identify who the players are for a particular chemical and then how EPA should reach out to those players for the different parts of the statute. However, we do recognize that EPA is going to likely need to assess fees on multiple manufacturers and maybe processors at one time. So there are some points we want to note.

First, we propose that EPA would initiate this fee only on manufacturers and not processors. We feel that manufacturers have the primary responsibility for chemical entry into commerce in the U.S., and we note that the statute only allows manufacturers, not processors, to request a risk evaluation. If EPA does decide to include processors in fees for specifically a risk evaluation of a substance, then we feel that EPA can do that in a second tier. You currently do that in your TSCA Section 4 rules in terms of how you apply TSCA Section 4 test rules to manufacturers in Tier 1 and then processors in Tier 2. We are going to follow up with some written comments in this space as well.

Second, we think that it would be appropriate to include some exemptions in terms of who would be required to pay fees. We think that there are some exemptions in your current TSCA

rules that could be reviewed and woven into your fee system. Some examples include how you treat non-isolated fee systems, byproducts, R&D substances, chemicals produced incidentally, etc. By applying these exemptions, some entities would not be required to pay the fees.

Third, it's going to be very difficult to identify companies that are subject to the fee if EPA requires manufacturers and processors to pay fees upfront for a certain TSCA statute. The challenge will be ensuring that you identify those players early on in the process. Echoing comments from my colleague from the American Chemistry Council, to the extent that the fee focuses on one specific use condition that the activity is opened up through other uses is going to be very difficult to administer.

Finally, there should be some type of mechanism for companies to exit an EPA review or an EPA activity should they desire not to pay the fee. That's proportioned in terms of how large the fee is for that activity.

One additional comment I would like to note is that EPA might want to consider a type of fast track mechanism. For example, there's a fee now for a PMN. You could pay the fee plus 50 percent to get the PMN review done by 30 days versus 90 days. That might be something the agency could consider for various activities that you will charge for in this fee system. With that, I would like to say thank you.

Speaker 3: Dan Newton, Society of Chemical Manufacturers and Affiliates

My name is Dan Newton, Senior Manager of Government Relations at the Society of Chemical Manufacturers and Affiliates, also known as SOCMA. Thank you for the opportunity to share with you our perspectives on EPA's authority to collect fees for the administration of the Toxic Substances Control Act. We are the only U.S. based trade Association dedicated solely to the specialty chemical industry. Over 70 percent of our members are small businesses.

When stakeholders came together on the need for TSCA reform, there was broad support for requiring industry to pay some amount of fees to fund implementation of the new legislation versus relying solely on appropriations. Stakeholders also supported fees being dedicated to the TSCA program rather than going to the Treasury. The new law accomplishes these goals. As EPA considers how to structure these new fees, we have several overarching concerns.

The first is how narrowly fees will be dedicated. We believe they should be linked to the costs of the program under which they are charged. In particular, we want to make sure fees charged for pre-manufacture notice submissions are based solely on the cost of the new chemicals program. We are very concerned that PMN submitters could become an easy target

for subsidizing the management of existing chemicals because of the large number of new chemical notices submitted annually and the ease of charging for them. We think that Congress intended the fees charged for participation in the given program to be limited to EPA's costs to administer that program. That is the clear implication of the statutory limit on fees, that they be not more than reasonably necessary to defray the costs related to such chemical substance.

Our second concern is the size of fees for PMN. Where there was broad consensus that $2,500 was too low, we are hopeful EPA will consider a fee structure that's not overly restrictive to market entry. One of the problems with the old TSCA was that it created a bias toward continued use of existing chemicals. This was unfortunate because history has shown that new chemicals tend to be safer. EPA has demonstrated its ability to promote innovation by expeditiously reviewing roughly 1,000 new chemicals per year and still being protective of human health and the environment. It would be a shame if the number of new chemicals started to trend downward because PMN fees became a barrier to market. We support the current fee structure for new chemicals, which has the benefit of being straightforward and familiar to manufacturers. The current structure includes fees on PMNs, reduced fees on intermediates and small businesses, and the ability of submitters to consolidate numerous PMNs into one submission. EPA now has to refund a PMN submitter if EPA misses its 90 or 180 day deadline. We believe an appropriate timeframe to refund a submitter in such cases is within 30 days of missing the deadline. We recognize there may be opportunities to be creative and change the structure, and we are open to discussing new ideas.

Third, EPA has not charged fees for exemptions under section 5H. This includes test market exemptions, low volume exemptions, and low release load exposure exemptions. We believe the amended statute does not authorize EPA to change its practice and start charging fees for exemption applications. The Senate passed version of the bill explicitly spoke of charging fees for requesting an exemption under Section 5, but the final bill dropped that language. We strongly oppose the imposition of fees on such applications. Activities qualifying for an exemption tend to be restrictive in volume manufacturing methods and end use applications, and therefore, do not raise the same concerns regarding health or environmental risks that larger volumes do. Additionally, exemption notices have shorter review times and do not require as many EPA resources as PMNs, so there's a lot of innovation that occurs here. Also note there was a rule I read from 1995 where EPA acknowledged the incentive to not charge fees on exemptions in order to provide an incentive. EPA should simply include the cost of reviewing exemption applications in the aggregate cost that PMN fees are designed to recover.

Fourth, we strongly oppose charging any fees for confidential business information as Canada does. Penalizing CBI claims of fees is a disincentive to innovation. The new TSCA requires EPA

to review a substantial number of CBI claims, and EPA is authorized to recover those class. To do so, EPA should treat the cost of CBI reviews as part of the overhead for fees applicable to the relevant program.

Fifth, the EPA should update the standard for what constitutes a small business for purposes of paying lower fees. At a minimum, EPA should increase the $4 and $40 million figures to account for inflation since they were last estimated.

We are planning a keeping the dialogue open with EPA and the Small Business Administration on this topic and would be happy to assist in any way. Thank you for the opportunity to share with you our perspective on fees.

Speaker 4: Jim Cooper, American Fuel and Petrochemical Manufacturers

I'm Jim Cooper with American Fuel and Petrochemical Manufacturers. The order of the points I'm going to make is not based on priority. First, I agree with Mike Walls that estimates for the costs for some of the work would go a long way in establishing appropriate fee structures. The PMN fees, in particular, need to be reasonable because that is where innovation lies. Regarding exemptions, intermediates, and things of that nature, they require much less time, and that has to be taken into consideration. We also would like to see no fees at all for exemptions, but if there's going to be a fee for service, it needs to be very, very low and very reasonable because that is where a lot of the test marketing comes in, and if the fee were high, it would really squash a lot of innovation before somebody could get a customer base.

For the manufacturer request evaluations, the scope should be left up to the sponsor unless EPA can identify other uses and players in the market that they think would be appropriate. You've got potential scenarios where a manufacturer might only want to sponsor something on behalf of a specific processor. For example, let's say they know what the specific uses are and that's what they are willing to do and that is their market. They may not have an interest in other markets, and that's got to be sorted out sooner rather than later.

With consortia, in programs where folks got together voluntarily and sorted it out among themselves, I'm not aware of anything that had to go to dispute resolution, and I used to manage groups myself back in the day. Since that is the case, EPA should play a very limited, but an important role nonetheless, in helping ID other players that are in the market. They can do that through some Section 8 work and not rely on CDR for everything, especially when it comes to processors. If there's something in particular that EPA wants to target, do a paired rule to find out who the processors are in those markets and who's using those chemicals. And then within the consortia, allow the manufacturers and processors to get together to see if they

can hash things out. Yes, this is a little bit new here in the U.S., but they've been doing it in Europe. Allow that first and then EPA can play a dispute resolution role if something can't be worked out.

And we agree that fees should be aligned with services, and that's why it's going to be important to at least do a best guess on those things. As far as the CBI fees are concerned, we do not want to get into a thing where we penalize those who have a competitive advantage by having a unique molecule or a unique use. That's where a lot of U.S. innovation comes from and that's why so many people choose to introduce new molecules into this country versus other places. We want to try to preserve that as much as possible.

That all being said, I guess from lowest to highest for right now – these are initial thoughts – your Section 4 is probably going to be the lowest because there is just not a lot of work as long as nothing can be seen or perceived as a tax. That seemed to be very important to certain parties, so we want to make sure there's a very specific service and that the fee is aligned with the magnitude of the service. And then with CBI, again, we don't want to create that big disincentive to even claim CBI especially for the smaller players where that is the crux of their business, trying to keep things secret from the larger competitor who could come in and undercut them at any time. Obviously Section 5 requires work, and Section 6 is going to require even more work. So from lowest to highest, that is probably initially the thinking of API. Section 6 is going to require full-blown risk assessments, and that's going to obviously require a lot of work on EPA's part. Again, thank you for the opportunity. These are always valuable discussions, and we look forward to more.